

REMARKSDISCUSSION OF CLAIMS

In the Office Action, claims 1-5, 8, and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 5,330,507 to Schwartz in view of U.S. Patent Number 6,006,134 to Hill et al.

In the Office Action, claims 27, 28, and 31-33 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Number 6,157,862 to Brownlee et al.

In the Office Action, claims 6, 7, and 12-26 are allowed over the prior art of record.

In the Office Action, claims 9, 10, 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In response thereto, claims 27-33 have been amended. Accordingly, claims 1-33 are now pending. Following is a discussion of the patentability of each of the pending claims.

Independent Claim 1

Claim 1 recites a method for controlling a patient's heart rate. The method comprises transvenously positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch, positioning an atrial electrode in the patient's atrium, detecting the patient's atrial rate, and delivering stimulation pulses to the vagal electrode when a fast atrial rate is detected. The stimulation pulses are delivered at a level that reduces the atrial rate to a normal operating range.

The *Schwartz* reference discloses a method and apparatus for effecting vagal stimulation to prevent or interrupt tachyarrhythmias. Stimulation of the vagus nerve is provided by placing electrodes (74, 76) around the left and right vagus nerve bodies

(see Figures 1 and 2). The electrodes are coupled to a pair of electrical leads (68, 78) at a distal end, and the leads are coupled to a nerve pulse generator (126).

The *Schwartz* reference does not disclose or suggest transvenously positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch. In the *Schwartz* reference, the electrodes are the cuff-type which are surgically implanted around the vagus nerve or the impalement-type which are implanted within the vagus nerve. Such placement of the electrodes typically requires very invasive surgery via the neck, which produces a high risk to nerve damage.

The *Hill et al.* reference discloses an electro-stimulation device having a transvenous lead positioned within the internal jugular vein to stimulate the left vagal nerve (see Figure 16). Nowhere does the *Hill et al.* reference disclose or suggest stimulating the vagus nerve by transvenously positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch.

The *Brownlee et al.* reference discloses a single pass lead system having a coil electrode (36) located in the superior vena cava to defibrillate the heart. Nowhere does the *Brownlee et al.* reference disclose or suggest transvenously positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch and delivering stimulation pulses to the vagal electrode to reduce the atrial rate. In the *Brownlee et al.* reference, the superior vena cava coil electrode is adapted to defibrillate the heart, and the vagal electrode recited in claim 1, in combination with the stimulation pulses, is adapted to stimulate the vagus nerve to reduce the atrial rate.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2-5 and 8-11

Claims 2-5 and 8-11 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 7

Claim 7 is allowed over the prior art of record.

Independent Claim 12 and Dependent Claim 13

Claims 12 and 13 are allowed over the prior art of record.

Independent Claim 14 and Dependent Claim 15

Claims 14 and 15 are allowed over the prior art of record.

Independent Claim 16 and Dependent Claims 17-26

Claim 16-26 are allowed over the prior art of record.

Independent Claim 27

Claim 27 recites a cardiac stimulation system for controlling a patient's atrial rate. The system comprises a vagal module and a transvenous lead body. The vagal module determines operating parameters for vagal stimulation. The transvenous lead body has an atrial electrode and an electrode portion. The atrial electrode is capable of sensing atrial signals. The electrode portion is configured to be positioned with a patient's superior vena cava and dimensioned to make contact with the tissue proximate to the cardiac branch of the right vagus nerve, and the electrode portion is adapted to deliver stimulation pulses to the right vagus nerve to reduce the atrial rate.

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 27 is in condition for allowance.

Dependent Claims 28-33

Claims 28-33 depend from claim 27 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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